Effectiveness of open and arthroscopic rotator cuff repair (UKUFF): a randomized controlled trial

Abstract:

Uncertainty exists regarding surgical management of patients with degenerative tears of the rotator cuff but its use is increasing substantially, particularly arthroscopic surgery. We aimed to assess the effectiveness of arthroscopic and open rotator cuff repair. 273 patients were recruited to a randomized comparison (136 to arthroscopic surgery and 137 to open surgery) from 19 teaching and district general hospitals in the UK. The surgeons used their usual and preferred method of repair. The Oxford Shoulder Score (OSS) at 24 months was the primary outcome measure. Imaging of the shoulder was performed at 12 months after surgery. The trial is registered with Current Controlled Trials, ISRCTN97804283.

The mean OSS improved from 26.3 (SD 8.2) at baseline to 41.7 (SD 7.9) at 24 months for arthroscopic surgery and from 25.0 (SD 8.0) to 41.5 (SD 7.9) for open surgery. Intention to treat analysis showed no statistical difference between the groups at 24 months (difference in OSS score = -0.76; 95% CI -2.75, 1.22; p=0.452). The confidence interval excluded the pre-determined clinically important difference in the OSS of three points. The rate of re-tear was not significantly different between the two groups (46.4% for arthroscopic and 38.6% for open surgery (95% CI -6.9, 25.8; p=0.256). Healed repairs had the most improved OSS. These findings were the same when analysed per-protocol.

There is no evidence of difference in effectiveness between open and arthroscopic repair. The rate of re-tear is high in both groups, for all tear sizes and ages and adversely affects outcomes.

Introduction:

The prevalence of shoulder complaints is estimated to be 14%, with 1–2% of adults consulting their general practitioner annually regarding new-onset shoulder pain[1]. Rotator cuff pathology reportedly accounts for up to 70% of shoulder pain problems[2]. Disability of the shoulder can impair ability to work or perform household tasks and may result in time off work[3]. Shoulder problems account for 2.4% of all GP consultations in the UK and 4.5 million visits to physicians annually in the USA[4]. More than 300,000 surgical repairs for rotator cuff pathologies are performed annually in the USA, where the annual financial burden of shoulder pain management has been estimated to be US$3 billion [5]. Rotator cuff tear refers to structural failure in one or more of the four muscles and tendons that form the rotator cuff. It is estimated that the overall prevalence of tears is 34% and that risk increases significantly with age [6]. The most frequent indications for surgery are persistent and severe pain combined with functional restrictions that are resistant to conservative treatment. Higher rates of re-rupture are associated with repairs of larger tears, increased patient age and increased fatty degeneration of the cuff muscles [7,8]. High failure rates of 13–68% have been reported for surgical repair of rotator cuff tears [9,11]. Some studies have suggested that re-rupture rates are associated with poorer outcomes [12]. Between 1996 and 2006 there was a 254% increase (from 30.0 to 101.9 per 100 000 people per year) in use of rotator cuff repair in New York State, compared to a 78.3% increase in ambulatory orthopaedic surgery overall [13]. Similar increases have recently been reported in the UK with a 5 fold increase rates of surgery between 2001 and 2010 [14]. Open surgery involves the rotator cuff being repaired under direct vision through an incision in the skin. Arthroscopic surgery involves the repair being performed through minimally invasive arthroscopic portals where a camera is used to visualize the operative site on a monitor. Over the past 10 years the number of arthroscopic repairs has increased by 600%, compared to a 34% increase in open repairs [15]. There is conflicting evidence regarding the effectiveness of open or arthroscopic repair [16-23]. Proponents of arthroscopic rotator cuff surgery suggest that the procedure may have advantages by causing less damage to the overlying soft tissue. Arguably this causes less post-operative patient discomfort together with earlier return of movement. However, the success of the repair depends partly on the ability of the surgeon to achieve a secure attachment of tendon to bone. This may be more easily and reliably achieved by open surgery. Other potential disadvantages of the arthroscopic approach include longer operating

time. We conducted a randomised controlled trial to determine the effectiveness of open versus arthroscopic rotator cuff repair.

Methods:

Study design and participants

The design was a pragmatic multicentre parallel group comparative effectiveness randomised controlled trial (RCT) of open versus arthroscopic rotator cuff repair (UKUFF REC Reference Number 10/H0402/24). The study involved 19 UK centres and was conducted from November 2007 to December 2012. The trial was modified in 2009 with the removal of a non-operative intervention arm due to high rates of early cross-over to surgery. Patients had to be aged 50 years and over, have symptoms from a degenerative full thickness rotator cuff tear and have failed to respond to conservative care including physiotherapy and cortisone injection. Full inclusion and exclusion criteria are in the published protocol [24].

Interventions

Surgery was either arthroscopic (fixation of tendon to bone using only arthroscopic techniques) or open (fixation to bone under direct vision through a surgically created opening in the deltoid muscle). The precise technique and method of fixation was not prescribed and surgeons used their preferred and usual method. Details of the surgical technique used including the method of repair and theatre equipment used (e.g. types of anchor) were recorded, as well as the size of the tear, the ease of repair and the completeness of the repair. If the allocated surgical technique could not be carried out then any alternative procedure undertaken was recorded. Surgeons had to perform a minimum of five cases per year to be eligible to take part in the trial. The participating surgeons represented a cross-section of high, medium and low volume practitioners from both general and teaching hospitals.

Randomisation and masking

Recruitment of patients occurred via a two-step process. The patient's eligibility was assessed by the local consultant orthopaedic surgeon who introduced the trial to the patient using a prompt sheet and a patient assessment form. If patients agreed to take part, they were randomized using the automated randomization service provided by [redacted].

Allocation was minimized using surgeon, age (under 65 years and 65 and older) and size of

tear (small, medium, large and massive). After randomization the participant was considered irrevocably part of the trial for the purpose of the research, irrespective of what occurred subsequently. In view of the nature of the interventions patients were aware of treatment allocation.

Outcomes

The primary outcome measure was the Oxford Shoulder Score (OSS) completed at 24 months after randomisation. The OSS is measured on a scale between 0 and 48 with 48 indicating the best score. Secondary outcome measures included the assessment of functional outcome and patient health related quality of life. The outcomes assessed a range of symptoms often experienced with rotator cuff tears e.g. pain, weakness and a loss of function. Patient reported outcomes included the shoulder pain and disability index (SPADI), Mental health inventory (MHI-5) and the EuroQol five dimension scale (EQ-5D). Participants rated how pleased they were with shoulder symptoms at 12, and at 24 months after randomisation and their view of the overall state of their shoulder at 8, 12, 24 months after randomisation. Surgical complications intra-operative and post-operative at 2 and 8 weeks post-surgery and at 12, 24 months after randomisation were collected. All patients who underwent a rotator cuff repair were assessed with MRI or High definition ultrasound imaging at 12 months after surgery by an experienced clinician blinded to the treatment group.

Sample size

The sample size was constructed to detect a difference in OSS [27] 24 months post-operative score of 0.38 of a Standard Deviation (SD) for the comparison of arthroscopic versus open surgery at 80% power. This defined difference was based on our experience of developing the OSS score and using it in a variety of settings, where a 3 point score difference was deemed a clinically important difference.

The detectable difference of 0.38 was originally constructed by combining evidence from a direct randomized comparison with indirect (non-randomized) comparison data from the original non-operative arm. However, when that non-operative arm was dropped we reassessed the sample size with the aim of detecting the difference of 0.38 of an SD by direct randomized comparison data only. Attrition was expected to be low (10%) as were the effects of clustering of outcomes within surgeon (intra cluster correlation, ICC, less than 0.03) [28-30]. Both of these factors required the sample size to be inflated, however, the primary analysis

was to be adjusted for baseline OSS score which conversely allowed the sample size to be decreased by a factor of "1-correlation squared". Our previous studies showed that the correlation in the OSS score pre surgery to six months post surgery in patients similar to potential trial participants was 0.57. Assuming a conservative correlation of 0.5 implied that the sample size could be reduced by 25%, and still maintains the same power. Therefore, a study with a total of 267 participants was considered sufficiently powered to detect a clinically important change in each comparison, assuming attrition and clustering accounted for approximately 25% of variation in the data. The target level of power was 80% and clustering was by centre. An independent Data Monitoring Committee DMC met on four occasions and did not recommend any fundamental changes to the protocol.

Statistical analysis The primary statistical analyses were based on the intention to treat principle (all people randomized, irrespective of subsequent compliance with the randomized intervention). The outcomes were compared using repeated measures mixed models with centre as a random effect, and with adjustment for minimization variables (size of tear and age) and participant baseline values (where available) as fixed effects. Reflecting the level of noncompliance, the effect on the primary outcome of those participants that actually received an arthroscopic or open repair was estimated (a "per-protocol analysis") by the instrumental variable approach as described by Nagelkerke et al [25]. As with the intention to treat analysis, the model also adjusted for centre, minimisation variables (age; size of tear) and baseline OSS score. Learning effects (i.e. the surgeon performance improves throughout the trial) were tested for by developing a covariate for each surgeon that indicates the increasing surgeon experience in the trial (e.g. 1st patient randomised=1; 2nd=2 etc). This covariate was used in subsequent adjusted analyses to measure the size of trend in effects over time.

Pre-planned subgroup analyses were also undertaken by tear size (small vs medium/large) and age (≤65 versus 65+) using tests of interaction. Sub-group analyses were 2 sided tests at 1% significance. If a participant was followed up at 8, 12 or 24 months but was missing at baseline then the missing baseline data was replaced by the centre mean. Conservative levels of statistical significance ($p<0.01$) were sought reflecting the exploratory nature of these analyses.

Results

Between November 2007 and December 2012 we recruited 273 participants from 422 eligible patients across 19 centres. Baseline characteristics were balanced between the two

randomised groups (Table 1). Table 2 shows the type of procedure undertaken in each group. For the 136 participants randomised to receive arthroscopic surgical management, 63 (46.3%) underwent a full arthroscopic repair of a tear, 9 (6.6%) began as an arthroscopic procedure and converted to open, 28 (20.6%) underwent an arthroscopic procedure (that did not involve a repair of a tear) and 36 (26.5%) did not undergo any surgery. Of the arthroscopic procedures not involving a repair, a shoulder sub-acromial decompression was the most common. As such, 100 (73.5%) participants received the intended randomised arthroscopic surgical management, though only 63 (46.3%) received an arthroscopic repair. Of the 137 participants randomised to receive open surgical management, 85 (61.6%) underwent an open repair of a tear and 5 (3.6%) an arthroscopic repair. Some 24 participants underwent an arthroscopic procedure and the most common was a shoulder sub-acromial decompression. Twenty-three participants did not receive any surgery. The principal reasons for participants not progressing to surgery were related to medical conditions (primarily cardiac events) or the participants were asymptomatic and were not judged to be appropriate for either of the allocated procedures.

The size of tear was similar between groups. The mean operation time in minutes was statistically significantly lower in the open procedure group (open 57.2 minutes, arthroscopic 69.4 minutes; effect size -12.2; 95% CI -21.4 to -3.0, p=0.010) as was mean total time in the operating room (open 87.6 minutes, arthroscopic 100.3 minutes; effect size -12.7; 95% CI -23.5 to -1.9, p=0.021).

Three participants in the arthroscopic group and three in the open group required inpatient re-hospitalisation post-surgery. Two in each group required revision surgery. A single participant in each group presented with a postoperative complication. One with a deep infection requiring formal debridement. The other complication was a participant requiring longer stay in hospital following a continuous inter-scalene block in shoulder for postoperative pain relief and some bleeding during surgery. All complications and revision surgeries were managed within 17 months of randomisation. Three participants died while in follow-up (two arthroscopic; one open). The cause of death was not attributable to participation in the trial for either patient.

Follow-up at two weeks post-surgery is shown in Table 3. Very few participants reported being pain-free and approximately two thirds were taking painkillers. Of those participants that were employed, about 80% were still off sick. There were no clinically important differences between the groups. The eight week results were similar to the two week follow-

up with the exception that reported none or mild pain improved from 35% to 50% and the apparent concomitant effect of reducing painkiller use from 66% to 55% and increasing the number of participants returning to usual work from 28% to 55%. There were no clinically important differences between groups.

The pre-specified primary outcome was the OSS score at 24 months follow-up (Table 4 and Figure 2). The higher the OSS score the better the quality of life. Under ITT analysis there was no evidence of a difference between the groups (difference = -0.76; 95%CI -2.75, 1.22; p=0.452). The confidence interval was also small enough to exclude the pre-specified clinically important difference of 3 points. The per-protocol sensitivity analysis of the primary outcome produced a similar result to the ITT analysis though the confidence intervals were much wider (difference = -0.46; 95%CI -5.30, 4.39; p=0.854). There was no evidence of any differences between the groups in any of the health status measures at all follow-up times. OSS increased markedly from baseline (mean = 25.7) to eight months (mean = 36.5) and continued to increase thereafter (at a much slower rate) to 24 months (mean = 41.5).

The rate of re-tear was similar, 46.4% for arthroscopic versus 38.6% for open surgery (Relative effect: OR 1.52; 95% CI 0.84, 2.75; Absolute risk difference 9.5%; 95%CI -6.9, 25.8; p=0.256) (Table 5). The OSS demonstrated a consistent pattern within each group, whereby the impossible to repair participants had the worse OSS, the re-tears a slightly better OSS and finally the participants with no tears had the most improved OSS.

The OSS improved from 26.3 (SD 8.2) at baseline to 44.5 (SD 4.1) for the arthroscopic group and 25.0 (SD 8.0) to 43.6 (SD 5.8) for the open group. The next best results were for the repaired tears that re-tore which improved to 41.8 (SD 8.8) for the arthroscopic group and 40.8 (SD 7.6) for the open group. The worst results were seen in the tears impossible to repair; which improved to 37.3 (SD 6.1) for the arthroscopic group and 35.1 (SD 9.7) for the open group.

There was no evidence that any of the subgroups were statistically significantly different at the 1% level (p= 0.843 for tear size and p=0.024 for age). The statistical model to investigate any trend in OSS at 24 months as surgeon experience increased during the trial did not demonstrate any significant learning effect (trend in OSS +0.04 per procedure; 95%CI -0.21,0.29; p=0.744).

Discussion

This multicentre trial, conducted across 19 UK centres, is the largest trial of rotator cuff repair ever undertaken. Results demonstrated that there were no significant differences in effectiveness when tears are repaired arthroscopically or by open surgery. Both surgical techniques resulted in a significant improvement in the primary outcome - the change in Oxford Shoulder Score (OSS) between baseline and two years – and in all of the pre-specified secondary outcome measures which included the shoulder pain and disability index (SPADI), the EQ-5D and the Mental Health Inventory. The number of patients suffering significant complications was very low and less than the rate described by Moosmayer et al. [31] but similar to that described by Kukkonen et al [32]. The infection rate in this study was 0.7% and the rate of revision surgery 1.5%.

The mean difference in the OSS at two years between healed tears, re-tears and unrepairable tears was approximately three OSS points for each (six in total) with healed repairs faring best. The next best results were for the repaired tears that re-tore. The worst results were seen in the tears impossible to repair. The improvement in the patients who re-tore may be due to one or more of a number of factors. Although the scan revealed a re-tear the repair may have healed partially resulting in improved function and less pain. The interpretation of post-operative scans is not straightforward due to anatomical changes created by the surgery and determining the size of a re-tear is difficult and prone to error. It is conceivable that a proportion of the re-tears were smaller than the original tear and this may account for some of the improvement seen in patients with a re-tear. Also the subacromial decompression surgery and tissue debridement that was invariably performed in these cases may result in an improvement. Alternative reasons for the treatment effect include a period of rest after surgery, physiotherapy after surgery or placebo. It is clear that patients' symptoms can improve even after a long duration of symptoms with non-surgical treatment. 22/81 (27.2%) who withdrew from the surgery whilst on the waiting list for surgery reported resolution of symptoms indicating that some of the improvement seen in the surgical group may result from spontaneous resolution of symptoms. Re-tears were found in all sizes of tears. Previous studies have indicated that re-tear is more likely after repair of large and massive tears due partly to the increased difficulty in securely fixing tendon to bone without tension at the suture tendon interface and partly to the reduced healing potential in the tendons of larger tears [7-12]. We found no difference in rates of re-tear between small/medium and large/massive

tears. These earlier studies also link re-tear to advanced age. We found no difference in re-tear rates between those aged under 65 compared to 65 and over. This may be because the number of large and massive tears and patients aged over 65 were relatively small. However, given that this is the largest multicentre randomised controlled trial of rotator cuff repair ever undertaken these findings suggest that factors other than age and tear size are important contributors to the risk of re-tear after rotator cuff repair.

There remains uncertainty in the global surgical community regarding surgery for rotator cuff tear and the results of this trial are likely to influence care in the UK and globally. The study was carried out in 19 centres in the UK with wide geographical representation making the results highly generalizable to the real world setting in which rotator cuff repair is performed. The study had several limitations. The rate of withdrawal from the planned surgery was high. We believe this is likely to be a real phenomenon and reflects usual rates of drop out from waiting lists in the NHS. The reasons for withdrawal included the patient becoming asymptomatic and the development of other medical conditions that prevented surgery taking place. Levels of withdrawal were equal in both groups. The reason why patients did not receive a surgical repair were firstly because no tear was found (scan false positive) or secondly the tear was impossible to repair; either because it was too large, too retracted or the tissue quality did not allow secure fixation. The relative inaccuracy of pre-operative scanning in a real world setting compared to accuracy reported in the literature is worthy of further investigation. Recognising that caution must be used when interpreting the per protocol group, we nevertheless note that the interpretation of the outcomes and the lack of important difference between arthroscopic and open ITT groups was also observed in the per protocol data.

Previous studies have been small and either single centre or in a small number of centres and have not had the same generalizability as this trial. The best outcome was seen in patients where the repair had healed. Re-tear rates were high and were found in all sizes of tear and all ages of patient. New strategies to improve tendon healing are needed to improve patient outcomes.

Figure 1

Trial Profile

Figure 2

Mean and 95% CI of Oxford Shoulder Score across time for arthroscopic and open surgery for the intention to treat (ITT) and per protocol populations

Table 1

Baseline characteristics of participants

Table 2

Adherence to surgical management in each group

Table 3

Follow-up at 2 weeks post surgery

Table 4

Health status at 8, 12 and 24 months post surgery

Table 5

Imaging at baseline and 12 months post surgery

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Table 1

Baseline characteristics or participants for the intention to treat and per protocol populations

		Arthroscopic Surgery Group	**Open Surgery Group**
Results for all Patients (Intention to treat)		(n=136)	(n=137)
		n;mean (SD)	n;mean (SD)
Age (years)		136;62.9 (7.1)	137;62.9 (7.5)
Years with shoulder problem		136;2.6 (5.3)	137;2.5 (4.1)
Sex	Male	81 (59.6%)	88 (64.2%)
	Female	55 (40.4%)	49 (35.8%)
Handedness	Right handed	125 (91.9%)	115 (83.9%)
	Left handed	7 (5.1%)	17 (12.4%)
	Both	4 (2.9%)	5 (3.6%)
Highest qualification	None	63 (46.3%)	59 (43.1%)
	Secondary	41 (30.1%)	49 (35.8%)
	Higher	32 (23.5%)	27 (19.7%)
	Missing		2 (1.5%)

Employment Status	Full time	47 (34.6%)	58 (42.3%)
	Part time	18 (13.2%)	15 (10.9%)
	Homemaker	4 (2.9%)	5 (10.9%)
	Retired	59 (43.4%)	54 (39.4%)
	Unemployed	7 (5.1%)	4 (2.9%)
	Missing	1 (0.7%)	1 (0.7%)
Off sick		7 (10.8%)	6 (8.2%)
Working reduced hours		10 (15.4%)	7 (9.6%)
Not off sick or working reduced Hours		45 (62.9%)	76 (55.9%)
Missing		3 (4.6%)	2 (2.8%)
OSS		136;26.2 (8.1)	137;25 (7.9)
SPADI		136;60.9 (22.0)	136;61.6 (22.0)
SPADI pain		136;70.0 (19.5)	137;70.1 (20.5)
SPADI disability	136;55.1 (25.0)	135;56.4 (24.7)	
MHI5		136;22.5 (4.9)	137;22.9 (4.5)
EQ5D		135;0.548 (0.299)	136;0.519 (0.291)
Size of tear			
Small/medium	103 (75.7%)	103 (75.2%)	
Large/massive	33 (24.3%)	34 (24.8%)	
Method of diagnosing tear			
MRI		41 (30.1%)	36 (26.3%)
Ultrasound		87 (64.0%)	93 (67.9%)

Missing	8 (5.9%)	8 (5.8%)
Received no treatment on the Shoulder in the last 5 years	15 (11.0%)	10 (7.3%)
Received physiotherapy on the Shoulder in last 5 years		
Yes	77 (56.6%)	83 (60.6%)
No	41 (30.1%)	38 (27.7%)
Missing	18 (13.2%)	16 (11.7%)
Received cortisone injection In shoulder in last 5 years		
Yes	79 (58.1%)	83 (60.6%)
No	40 (29.4%)	35 (25.5%)
Missing	17 (12.5%)	19 (13.9%)
Received other treatment on the Shoulder in the last 5 years		
Yes	18 (13.2%)	28 (20.4%)
No	72 (52.9%)	61 (44.5%)
Missing	46 (33.8%)	48 (35.0%)

Table 2

Adherence to surgical management in each group

	Arthroscopic Surgery Group (n=136)	**Open Surgery Group** (n=137)
Received any surgery	100 (73.5%)	114 (83.2%)
Received an arthroscopic repair	63 (46.3%)	5 (3.6%)
Received an open repair After attempted arthroscopic repair	9 (6.6%)	
Received an open repair		85 (62.0%)
Received an another Operative procedure	28 (20.6%)	24 (17.5%)
Details		
Arthroscopic subacromial Decompression(ASAD)	*20(14.7%)*	*16 (11.7%)*
ASAD & excision distal clavicle	*1 (0.7%)*	*3 (2.2%)*
Biceps tenotomy	*2 (1.5%)*	
Capsular release	*1 (0.7%)*	*2 (1.5%)*
Partial thickness repair		*2 (1.4%)*

Not documented	*4 (3.0%)*	*1 (0.7%)*
Did not revceive intervention	36 (26.5%)	23 (16.8%)
Details		
Still Awaiting surgery when		
Study ended	*2 (1.5%)*	*2 (1.5%)*
Cancelled due to other		
medical problem	*11 (8.1%)*	*3 (2.2%)*
Complete withdrawal from study	*2 (1.5%)*	
Due to family commitments	*2 (1.5%)*	*1 (0.7%)*
No longer symptomatic	*7 (5.1%)*	*7 (5.1%)*
Patient deceased	*1 (0.7%)*	
Patient withdrew from waiting list for		
Unspecified reasons	*7 (5.1%)*	*7 (5.1%)*
Work commitments	*3 (2.2%)*	*2 (1.5%)*
Unknown	*1 (0.7%)*	*1 (0.7%)*

Table 3

Follow-up at 2 weeks post surgery

Results for all Patients	**Arthroscopic Surgery Group** (n=136)	**Open Surgery Group** (n=137)
Completed follow-up	94 (69.1%)	112 (81.8%)
Within the last 24 hours Have you worn a sling		
Yes	60 (63.8%)	78 (69.6%)
No	32 (34.0%)	31 (27.7%)
Missing	2 (2.1%(	3 (2.7%)
Within the last 24 hours How would you regard The worst pain from Your shoulder		
None	6 (6.4%)	6 (5.4%)
Mild	30 (31.9%)	34 (30.4%)
Moderate	36 (38.3%)	50 (44.6%)
Severe	17 (18.1%)	19 (17.0%)
Unbearable	3 (3.2%)	1 (0.9%)

Missing	2 (2.1%)	2 (1.8%)
Were you troubled by		
Pain from your shoulder		
In bed last night		
No, not at all	25 (26.6%)	25 (22.3%)
Yes, just at first 8 (8.5%)	6 (5.4%)	
Yes, some of the night	38 (40.4%)	44 (39.3%)
Yes, through the night	21 (22.3%)	35 (31.3%)
Missing	2 (2.1%)	2 (1.8%)
Within the last 24 hours		
Have you taken any		
Painkillers because		
Of your shoulder		
Yes	62 (66.0%)	76 (67.9%)
No	29 (30.9%)	34 (30.4%)
Missing	3 (3.2%)	2 (1.8%)
Are you currently		
Employed?		
Yes	46 (48.9%)	57 (50.9%)
No	46 (48.9%)	53 (47.3%)
Missing	2 (2.1%)	2 (1.8%)

If employed are you		
Off sick	38 (82.6%)	44 (77.2%)
On reduced duties	3 (6.5%)	5 (8.8%)
Working usual hours	5 (10.9%)	8 (14.0%)
And duties		

Table 4

Health status at 8, 12 and 24 months

OSS = Oxford Shoulder Score

MHI5 = Mental Health Inventory 5

EQ5D = Euroqol5 dimension

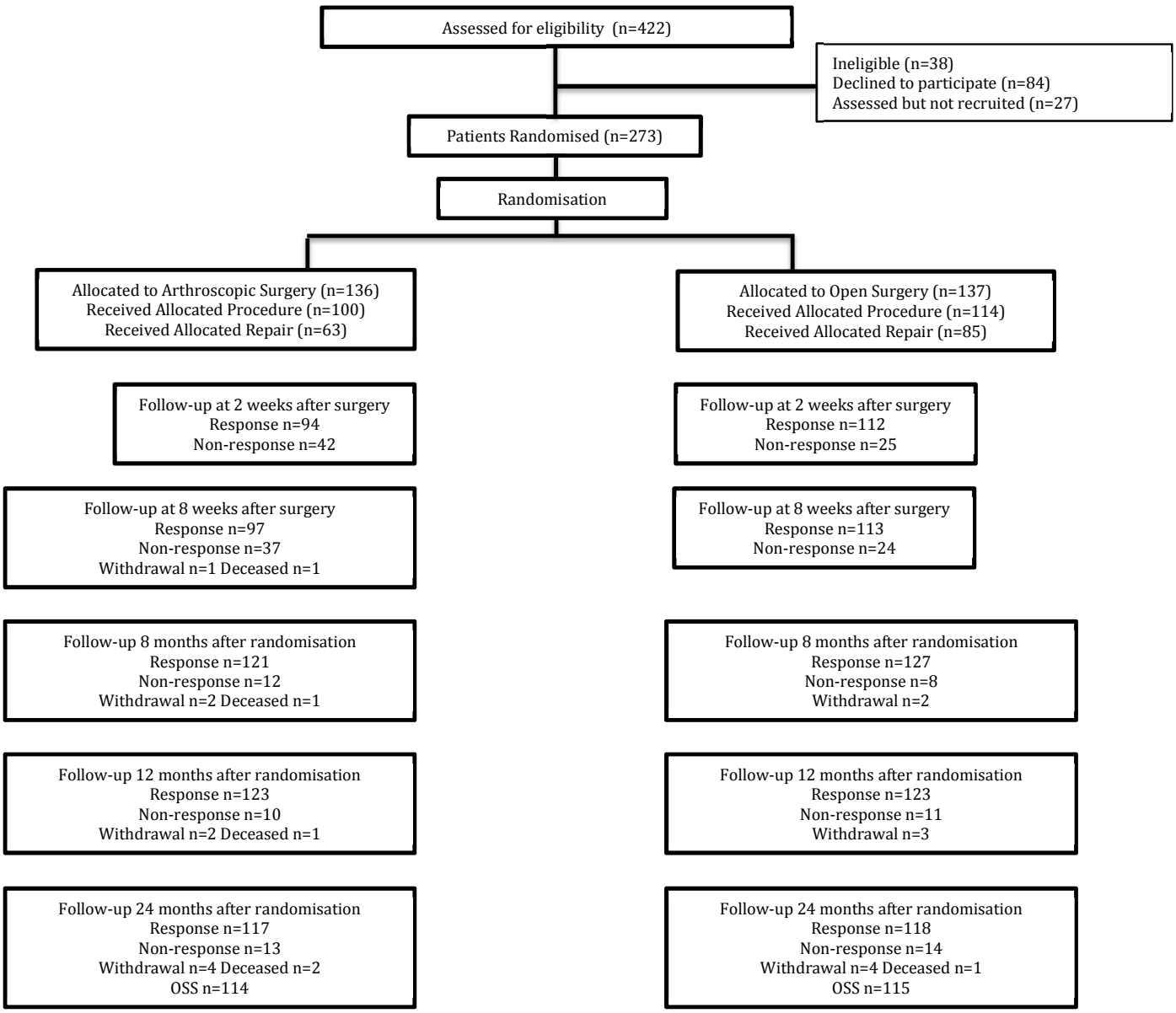
	Arthroscopic Surgery Group	**Open Surgery Group**	
Results for all Patients (Intention to treat)	(n=136)	(n=137)	p-value
	n;mean (SD)	n;mean (SD)	
OSS at baseline 129;26.3 (8.2)	131;25.0 (8.0)		
OSS at 8 months	121;36.1 (9.2)	127;37.0 (8.6)	0.200
OSS at 12 months	122;38.3 (9.5)	122;39.6 (8.5)	0.108
OSS at 24 months	114;41.7 (7.9)	115;41.5 (7.9)	0.452
MHI5 at baseline	128;22.4 (4.9)	130;22.9 (4.5)	
MHI5 at 8 months	118;23.8 (4.9)	124;23.8 (4.4)	0.500
MHI5 at 12 months	118;23.5 (5.0)	119;23.6 (4.6)	0.783
MHI5 at 24 months	116;24.4 (4.0)	118;24.3 (4.5)	0.648
EQ5D at baseline	129;0.551 (0.297)	131;0.518 (0.293)	
EQ5D at 8 months	120;0.680 (0.300)	124;0.700 (0.257)	0.296
EQ5D at 12 months	119;0.727(0.278)	118;0.711(0.300)	0.724
EQ5D at 24 months	116;0.76(0.235)	118;0.778(0.219)	0.163

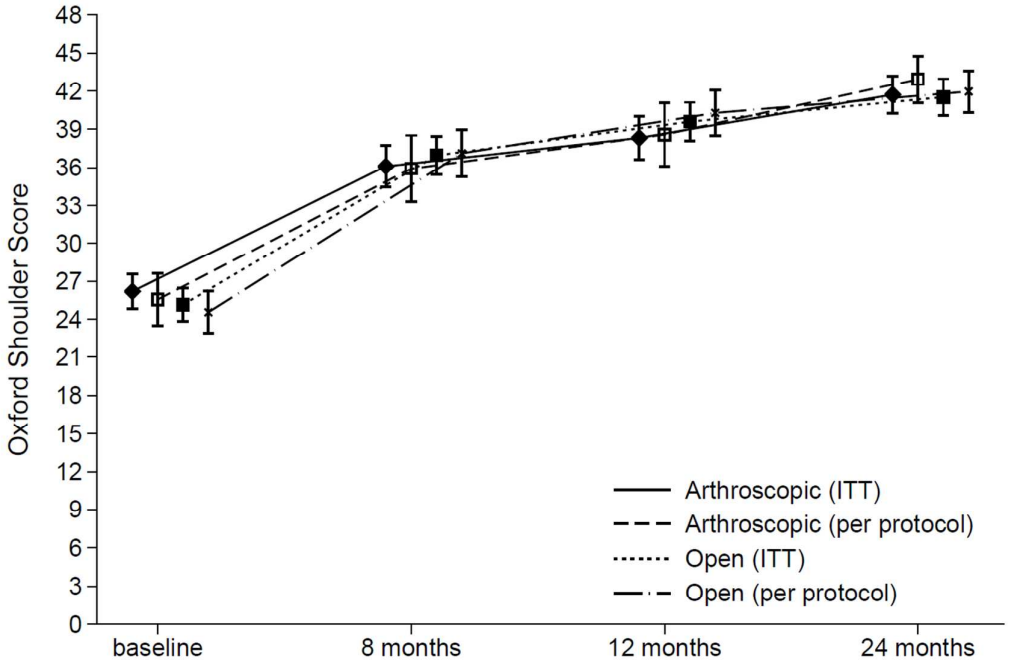
Table 5

Imaging at baseline and 12 months post surgery

	Arthroscopic Surgery Group (n=136)	**Open Surgery Group** (n=137)	p value
Size of tear			
Small/Medium	103 (75.7%)	103 (75.2%)	
Large/Massive	33 (24.3%)	34 (24.8%)	
Received any surgery	100 (73.5%)	114 (83.2%)	
Rotator cuff repairs			
Performed	72 (63 arthroscopic 9 arthroscopic converted to open)	90 (85 open, 5 arthroscopic)	
Scans performed at			
12 months	69	83	
Scan Results all tears			
Re-tear	32 (46.4%)	32 (38.6%)	0.256
Healed repair	32 (46.4%)	47 (56.6%)	
Inconclusive	1 (1.4%)	1 (1.2%)	
Missing	4 (5.8%)	3 (3.6%)	

Size of re-tear (all tears)		
Small/Medium	16 (50.0%)	20 (62.5%)
Large/Massive	13 (40.6%)	10 (31.3%)
Not clear	3 (9.4%)	2 (6.3%)
	n;mean (SD)	n;mean (SD)
Oxford Shoulder Score at 24 months (all tears)		
Healed repair	30;44.5 (4.1)	47;43.6 (5.8)
Re-tear	30;41.8 (8.8)	29;40.8 (7.6)
Impossible to repair	7;37.3 (6.1)	8;35.1 (9.7)


Assessed for eligibility (n=422)
Ineligible (n=38)
Declined to participate (n=84)
Assessed but not recruited (n=27)
Patients Randomised (n=273)
Randomisation
Allocated to Arthroscopic Surgery (n=136)
Received Allocated Procedure (n=100)
Received Allocated Repair (n=63)
Allocated to Open Surgery (n=137)
Received Allocated Procedure (n=114)
Received Allocated Repair (n=85)
Follow-up at 2 weeks after surgery
Response n=94
Non-response n=42
Follow-up at 2 weeks after surgery
Response n=112
Non-response n=25
Follow-up at 8 weeks after surgery
Response n=97
Non-response n=37
Withdrawal n=1 Deceased n=1
Follow-up at 8 weeks after surgery
Response n=113
Non-response n=24
Follow-up 8 months after randomisation
Response n=121
Non-response n=12
Withdrawal n=2 Deceased n=1
Follow-up 8 months after randomisation
Response n=127
Non-response n=8
Withdrawal n=2
Follow-up 12 months after randomisation
Response n=123
Non-response n=10
Withdrawal n=2 Deceased n=1
Follow-up 12 months after randomisation
Response n=123
Non-response n=11
Withdrawal n=3
Follow-up 24 months after randomisation
Response n=117
Non-response n=13
Withdrawal n=4 Deceased n=2
OSS n=114
Follow-up 24 months after randomisation
Response n=118
Non-response n=14
Withdrawal n=4 Deceased n=1
OSS n=115


Oxford Shoulder Score
48
45
42
39
36
33
30
27
24
21
18
15
12
9
6
3
0
baseline
8 months
12 months
24 months
Arthroscopic (ITT)
Arthroscopic (per protocol)
Open (ITT)
Open (per protocol)